UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,789	05/15/2001	Pablo Rubinstein	63475/267	9553

7590 02/08/2005

Craig J. Arnold
AMSTER, ROTHSTEIN & EBENSTEIN
90 Park Avenue
New York, NY 10016

EXAMINER	
BIANCO, PATRICIA	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,789	RUBINSTEIN ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/5/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,27-36,39-49,52-60 and 62-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,27-36,39-49,52-60 and 62-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5th, 2004 has been entered.

The After Final Amendment filed September 13th, 2004 has been entered as requested at the time of filing the RCE papers. In said amendment, claims 25, 41, 49, 54, 64, & 73 were amended.

Claims 25, 27-36, 39-49, 52-60, & 62-73 remain pending.

Response to Arguments

Applicant's arguments with respect to claims 25, 27-36, 39-49, 52-60, & 62-73 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claim 36 is objected to because of the following informalities: it is unclear if applicant is claiming the anticoagulant to be all 3 anticoagulants because the language "wherein the anticoagulant is Citrate, Phosphate, and Dextrose" implies all three. If not,

it is suggested to use language such as "wherein the anticoagulant is ***one of*** Citrate, Phosphate, and Dextrose" or "wherein the anticoagulant is ***chosen from the group comprising/consisting of*** Citrate, Phosphate, and Dextrose". Appropriate correction is required.

Claim Rejections - 35 USC § 102/35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 27, 30-36, 39-42, 45-49, 52-55, 58-60, 62-65, & 68-73 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Boyse et al. (5,004,681).

It is the position of the examiner that the "therapeutic product" claimed is mostly separated white blood cells and a cyroprotective agent that has a cell viability greater than 80% (as required by independent claims 25, 41, 64 & their dependents) or viability greater than 90% (claim 54 & its dependents). Boyse et al. discloses cryopreservation

of hematopoietic stem and progenitor cells (i.e. white blood cells) of blood therefore anticipates or, in the alternative, renders obvious the claimed invention. Boyse et al. discloses that the cells have a cyroprotective agent in a low concentration to result in viable cell counts of greater than 80% and 90% (see Table III for Viability percentages & col. 22, line 25-col. 24, line 10). The cells may be obtained from cord blood and/or placental blood (col. 12, lines 54-60). The blood had an anticoagulant, such as ACD, added to it and therefore the cells will inherently have residual anticoagulant in the product. The cells also will have a cyroprotective agent added to them, such as DMSO or dextran. With respect to the use of DMSO and its concentration, Boyse et al. states that a low concentration of DMSO is used (col. 12, lines 25-68). Applicant also claims that the white cell viability is tested using DNA fluorescence stain (claims 39, 52, 62, & 71). This limitation is seen as a recitation of the intended use for calculating the product viability and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed product from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In the alternative, the claims are seen to be rejected as being obvious over Boyse et al.. With respect to the cell viability being greater than 80% or greater than 90%, it would be obvious to modify the concentration of cyroprotective agent added to the cells to achieve greater than 80% or 90% viability, %, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ

233. With respect to the claimed limitations specific to the concentrations of DMSO used (10% DMSO and 1% DMSO), the osmolarity of the product not more than 300 milliosmols and to the limitations requiring the volume of the product being contained in a volume of 3 mm to 20mm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a concentration of DMSO to be either 1% or 10%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, since Boyse et al. discloses that a low concentration of DMSO is used such general conditions are met. With respect to the osmolarity of the product is not more than 300 milliosmols, it would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve this osmolarity, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 29, 43, 44, 56, 57, 66 & 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse et al. ('681) in view of Livesey et al. (5,622,867). Boyse et al. discloses the invention substantially as claimed, see rejection supra. Boyse et al., however, fails to disclose specifically of using a cyroprotective agent of DMSO being diluted to 50% with dextran. Boyse et al does teach that the cryoprotectant agent used may be chosen from DMSO or dextran.

Livesey et al. teaches of cryopreserved cells that have cyroprotective agent added to them to preserve cell viability. The cyroprotective agent may be DMSO, or dextran, individually or in combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a concentration of DMSO to be diluted DMSO to 50% with dextran, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boyse et al. (6,461,645) discloses an analgous composition of cells, such as leukocytes, containing a cryoprotectant agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 7th, 2005

PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
Art Unit 3762